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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,158	08/25/2003	Kenneth MC Cheung	V0690.0008/P008	3550
<div>Charles E. M DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 41st Floor 1177 Avenue of the Americas New York, NY 10036-2714</div>				
<div>7590 09/14/2007</div>			<div>EXAMINER SHAFFER, RICHARD R</div>	
			<div>ART UNIT 3733</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 09/14/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,158	Applicant(s) CHEUNG ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22, 28, 29 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, 28, 29 and 32-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-22, 28, 29 and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al (US Patent 5,290,289). Sanders et al disclose a method for correcting spinal deformities comprising: providing a nearly constant (but adjustable) correction force with a Nitinol (a material with superelastic/pseudoelastic and shape memory properties) rod (**Column 5, Lines 50-65**). The rod is first pre-contoured to assume normal kyphosis and lordosis (**Column 5, Lines 50-55**) and then deformed to conform to the spinal deformities. The rod is capable of having the force adjusted by remotely heating the rod with a radio frequency induction heater (**Column 7, Lines 55-60**). The heating allows for individual adjustment of the rod sections for corrective force. In regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited, and when considering **Figure 2**, it is clear the rod applies force to a side of the vertebra. Nitinol anchor members (bone clamps and blockers; **Column 3, Line 5 through Column 4, Line 11**) are utilized to limit the rod from rotational movement.

Claims 20-22, 28, 29 and 32-43 rejected under 35 U.S.C. 102(b) as being anticipated by Cool et al (European Patent Application 0 470 660 A1). Cool et al disclose a method for correcting spinal deformities comprising: providing a correction force with a Ti-Ni (1:1 ratio so it is Nitinol) alloy rod (**Column 4, Lines 54-55**) having various cross-sections (i.e. square, rectangular) and various transition temperatures which can adjust the force applied; a force is present operatively by a nearly constant corrective force which is activated by the body's own heat (**Column 1, Line 1 through Column 2, Line 26**) during the procedure. The rod is pre-formed to match the spinal rod (**Column 3, Lines 27-59**) and deformed to conform to the spinal deformity (**Column 3, Lines 20-26**) in order to be fixed by anchors (**6**), which act to limit the correction device from rotational movement. Again, in regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited.

Claims 20-22, 28, 29, and 32-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Drewry et al (US Patent 6,783,527). Drewry et al disclose a method for correcting spinal deformities comprising: providing a constant (inherent) correction force through the use of tethers (**80**) made of superelastic Nitinol (**Column 3, Lines 60-65**) which generates the correction force at body temperature; the forces activated during surgery and are adjusted/set by tensioning the tethers (**80**) by the surgeon. The tethers (**80**) are anchored by elements (**30** and **50**) that are formed of Nitinol (**Column 4, Line 66 through Column 5, Line 6**) which limit rotational movement of the tether. The overall device can be placed anteriorly or posteriorly (**Column 3, Lines 48-55**). The

device is deformed to conform to the spinal deformities (inherent due to it being tensioned and anchored to the vertebrae).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al in view of Cool et al. Sanders et al disclose all of the claimed limitations except for the correction force being generated at body temperature, but did mention that prior devices loaded the spine at once instead of constant incremental steps. Cool et al teach a similar device that employs using Nitinol to be active at body temperature. It would have been obvious to one having ordinary skill in the art at the time of invention to provide for a rod designed to provide a correction force at body temperature instead of utilizing an external heating as a matter of substitution with predictable results.

Claims 44 and 45 rejected under 35 U.S.C. 103(a) as being unpatentable over Cool et al in view of Sanders et al and Drewry et al. Cool et al disclose all of the claimed limitations except for anchor elements made of Nitinol. Sanders et al and Drewry et al both teach using anchor elements made of Nitinol in order to quickly and firmly attach the rod/tether to bone. It would have been obvious to one having ordinary skill in the art at the time of invention to make the anchor elements of Cool et al out of Nitinol to allow for quick and firm attachment to the rod.

Response to Arguments

Applicant's arguments filed on May 7th, 2007 have been fully considered but they are not persuasive.

In regard to Sanders et al, applicant states that the reference fails to disclose a "constant force." Sanders et al inherently disclose a "constant force" due to utilizing the same idea of rod as Cool et al who repeatedly state (in **abstract; Column 2, Lines 45-50; Claim 1**) that the force is "constant."

In regard to Cool et al, applicant states that Nitinol is not a "superelastic material." Nitinol exhibits both superelastic and shape memory properties, therefore it is a superelastic material as well as a shape memory material. Applicant is encouraged to read about Nitinol in the non-patent literature submitted with this Office Action.

In regard to Drewry et al, applicant argues again that the force is not constant and attempts to state that the device of Drewry et al follows Hook's law. Drewry et al utilize a "superelastic Nitinol" (see **Column 3, Lines 60-65**). Therefore, it exhibits non-linear characteristics and therefore a constant force. This is well known in the art and supported by each non-patent literature article submitted to applicant for his review. Further, even if such evidence was not submitted, the examiner is at a loss on how applicant thought a difference existed between his superelastic Nitinol and Drewry's superelastic Nitinol given the same material and thus the same material properties.

In regard to applicant's argument stating that Drewry et al do not disclose the device active at body temperature, superelastic characteristics are exhibited at

isothermal conditions (not requiring additional heat). Therefore, the device is active at body temperature because it would be nonfunctional otherwise.

Conclusion

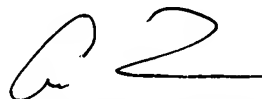
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
August 24th, 2007



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Continuation of Attachment(s) 6). Other: NPL Documents from www.nitinol.com.